

## Information

### Text of Required Patient Information for IUD's

*Editor's Note: Effective November 7, 1977, new regulations established by the Food and Drug Administration will require manufacturers of intrauterine birth control devices (IUD's) to print patient brochures describing the uses and possible risks associated with IUD's. The manufacturers must ensure that enough of these brochures are produced to make them readily available in clinics, physicians' offices and health facilities. Under the regulations, physicians must give women an opportunity to read a copy of the brochure and ask questions before deciding to have an IUD inserted. The following is the text that the brochures will use, as published in the Federal Register on May 10, 1977.*

#### **Patient Information**

THIS BROCHURE provides information on the use of intrauterine contraceptive devices (IUD's). There are other birth control methods that may be suitable. Before deciding which type of birth control method to use, you should read this brochure and have the opportunity to discuss fully with your doctor any questions you may have about the IUD and other methods of contraception.

#### **Preinsertion Information—What You Should Know About the IUD**

IUD's are small articles of various sizes and shapes which are inserted into the uterus (womb). The purpose of the IUD is to prevent pregnancy.

How the IUD prevents pregnancy is not completely understood. Several theories have been suggested. IUD's seem to interfere in some manner

with the implantation of the fertilized egg in the lining of the uterine cavity. The IUD does not prevent ovulation.

The effectiveness of the IUD is measured by the pregnancy rate of women who use it and the rate of adverse reactions and side effects requiring removal of the IUD.

#### **Use-Effectiveness**

Different pregnancy and adverse reaction rates have been reported with the use of different IUD's. Because these rates are usually derived from separate studies conducted by different investigators in several population groups, they cannot be compared with precision.

In clinical trials with (\_\_\_ name of IUD \_\_\_) \_\_\_\_\_ patients completed \_\_\_\_\_ cycles or months in use. The incidence of unplanned pregnancies was \_\_\_\_\_ per 100 women years or \_\_\_\_\_ women out of 100 became pregnant in a year while using an IUD. The incidence of adverse reactions requiring medical removal of the IUD is \_\_\_\_\_ per 100 woman years or \_\_\_\_\_ women out of 100 discontinued using the IUD for medical reasons.

#### **What You Should Tell Your Doctor**

Before you have an IUD inserted, you should tell your doctor if you have ever had, or suspect you have ever had, any of the following conditions which might make the IUD unsuitable as a method of contraception for you:

Abnormalities of the uterus (womb); Allergy to copper; Anemia; Bleeding between periods; Cancer of the uterus (womb) or cervix; Fainting attacks; Heart disease; Heart murmur; Heavy menstrual flow; Infection of the uterus (womb) or cervix; Pelvic infection (pus in the fallopian tubes); Prior IUD use; Prior uterine surgery; Recent abortion or miscarriage; Recent pregnancy; Severe menstrual cramps; Suspected or possible pregnancy; Suspicious or abnormal "Pap" smear; Unexplained genital bleeding; Vaginal discharge or infection; Venereal disease; Wilson's disease.

#### **Adverse Reactions**

The following adverse reactions and side effects have been reported and may occur after the IUD is inserted:

Anemia; Backache; Blood poisoning (septicemia); Bowel obstruction; Cervical infection; Complete or partial expulsion; Cysts on ovaries and tubes; Delayed menstruation; Difficult re-

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moval; Embedment; Fainting at the time of insertion or removal; Fragmentation; Intermenstrual spotting; Internal abdominal adhesions; Pain and cramps; Painful intercourse; Pelvic infection; Perforation of the uterus (womb) or cervix; Pregnancy; Pregnancy outside the uterus (womb) (tubal or ovarian); Prolonged or heavy menstrual flow; Septic abortion (infected miscarriage) followed in some cases by blood poisoning (septicemia) which can lead to death; Spontaneous abortion (miscarriage); Vaginal discharge and infection.

If you decide on the IUD as your method of birth control, read the following information and instructions carefully. Please keep this brochure so that you may refer to it. If you have any questions, consult your doctor.

### **Postinsertion Information Description (To Be Supplied by Manufacturer)**

Description shall include the following information:

1. Proprietary or established name of the IUD; 2. Model; 3. Physical dimensions (size and shape); 4. Composition (metal or plastic); 5. Color and number of the tail or threads; 6. Other characteristics.

### **Directions for Use**

1. *Checking your IUD.* A tail or thread is attached to the IUD so you can check to see if it is still in place since the IUD can come out of the uterus (womb) without your knowing it. This occurs most often during or right after a menstrual period.

Follow these steps to make sure your IUD is in place:

- (a) Wash your hands; (b) Assume the squatting position or seat yourself on the toilet; (c) Insert the index or middle finger high in vagina and locate the cervix (mouth of the uterus [womb]). The cervix feels firm like the tip of your nose; (d) Feel for the tail or thread of the IUD which should be in the cervix high in your vagina; (e) If you can feel the tail or thread it is likely that the IUD is in place and working. You should not pull on the tail or thread. This may displace the IUD; (f) After each menstrual period, you should check to make sure the tail or thread is in place in the cervix. You may check for the tail or thread more often if you wish; (g) If you think the IUD has come out or has been displaced (e.g., you cannot

feel the tail or thread or you can feel the IUD itself), use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), until you can be checked. (These alternative methods are not as effective as the IUD.) Call your doctor for an examination; (h) You should return to see your doctor as soon as possible after your next menstrual period, after insertion of your IUD, but no later than 3 months after insertion. This will allow the doctor to make sure that the IUD is in the correct position; (i) After your first checkup, you should be checked at least once a year by your doctor.

2. *Continuation and removal.* While you are wearing the IUD, you may use tampons and take douches, if this is your usual practice. With some IUD's, you may wear the IUD until you wish to become pregnant. With other IUD's it is necessary that they be replaced every year or so in order for you to continue being protected against pregnancy. Check with your doctor concerning this. You should return to your doctor if you wish to have the IUD removed.

### **Side Effects**

The following may occur during or after the IUD is inserted:

- (1) Some bleeding occurs following insertion in most women. Because of this, your doctor may choose to insert your IUD during or at the end of your menstrual period. This also reduces the possibility that you are pregnant at the time of IUD insertion. (2) Bleeding between menstrual periods, usually in the form of spotting, may occur during the first 2 or 3 months after insertion. The first few menstrual periods after the insertion may be heavier and longer. If these conditions continue for longer than 2 or 3 months, consult your doctor. (3) Pain, usually in the form of uterine cramps or low backache, may occur at the time of insertion and last for a few days. Simple pain medication usually relieves the cramping. (4) Fainting may occur at the time of insertion or removal of an IUD. This passes quickly and is not usually serious. (5) The IUD may be expelled during the first two or three menstrual cycles following insertion. Expulsion increases the risk of an unplanned pregnancy. Although not as effective as the IUD, the use of a second contraceptive method, such as a contraceptive vaginal foam, cream, or jelly, or condoms (rubbers) is recommended.

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### Warnings

1. Call your doctor for any of the following reasons:

(a) *Severe or prolonged bleeding.* If the flow is heavier and lasts much longer than your usual menstrual flow, you may need to have the IUD removed to prevent the development of anemia. (b) *Pelvic pain and cramps.* This could mean an infection has developed requiring treatment. (c) *Exposure to venereal disease (VD).* If exposure to venereal disease is suspected, report for examination and treatment promptly. Failure to do so could result in serious pelvic infection because use of an IUD in itself does not prevent venereal disease. (d) *Tail or thread disappearance.* If you cannot feel the tail or thread coming through the cervix, it is possible that the IUD has been expelled or displaced or that perforation has occurred. If any of these has occurred, you are no longer protected from becoming pregnant. Use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers) until you can be checked. (These alternative methods are not as effective as the IUD.)

2. Do not undergo medical diathermy (including shortwave or microwave treatments to the abdomen or lower back areas if you are wearing

a metal IUD. These treatments may cause heat injury to the surrounding tissue.

### Special Warning About Pregnancy with an IUD in Place

Some women become pregnant while using an IUD. If you miss your menstrual period, or if you have a scanty flow during your period, or if you suspect that you might be pregnant, see your doctor right away. Serious complication of sepsis (severe infection), septic abortion (infected miscarriage), and death have occurred when a pregnancy continues with an IUD in place. Most of the occurrences of these serious complications have been reported in the middle third of pregnancy.

If your doctor confirms that you are pregnant, he should remove the IUD if the tail is visible. Removal of an IUD in pregnancy decreases the likelihood of serious complications.

If removal of your IUD proves to be difficult, you and your doctor should discuss at that time the question of continuing the pregnancy in view of the serious complications that may occur. In reaching a decision as to whether or not to have an abortion, it should be remembered that the risks associated with terminating a pregnancy increase with the length of time you are pregnant.

## Treatment for Venous Thrombosis

What treatment is indicated for a patient with venous thrombosis?

If a patient is up and walking about, the clot that is in the venous system tends to occlude the lumen. The clot itself is wider, it is shorter and one would have then a blockage at this particular point. Put this patient in bed and . . . the clot . . . becomes longer, it becomes thinner and it becomes nonobstructive. And the blood can flow past, and edema and swelling do not result. This is why one of the standard treatments is still to put these patients in bed as soon as symptoms of venous thrombosis develop.

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